IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ : FENFLURAMINE/DEXFENFLURAMINE) : MDL DOCKET NO. PRODUCTS LIABILITY LITIGATION : 2:15 MD 1203

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

V.

AMERICAN HOME PRODUCTS CORPORATION

THIS DOCUMENT RELATES TO:

:

DENISE SWANIGAN CLAIM NUMBER 183/00 3375714 ARBITRATION NUMBER 937

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. April 15, 2008

Denise Swanigan ("Ms. Swanigan" or "claimant"), 1 a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth² seeks benefits from the AHP Settlement Trust ("Trust"). The Trust denied Ms. Swanigan's claim for Matrix Compensation Benefits ("Matrix Benefits"). Matrix Benefits compensate claimants for medical conditions caused by the diet drugs Pondimin or Redux.3

^{1.} Ms. Swanigan is pro se.

^{2.} Prior to March 11, 2002 Wyeth was known as American Home Products Corporation.

^{3.} Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants (continued...)

<u>See</u> Settlement Agreement § IV.B. Ms. Swanigan appealed the Trust's adverse Final Determination, and the matter was referred to arbitration. <u>See id.</u> § IV.C.4.i. The Arbitrator issued a Report and Award affirming the Trust's determination.

Ms. Swanigan has now appealed to this court as permitted under the Settlement Agreement. See id. She argues that she provided sufficient information to the Trust to satisfy her burden of proof. We apply a clearly erroneous standard of review to the Arbitrator's findings of fact and conduct a plenary review of conclusions of law. See First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938, 947-49 (1995). The decision of this court is final and binding. See Settlement Agreement at § IV.C.4.1.

Ms. Swanigan submitted a signed "Pink Form" to register with the Trust dated August 24, 2000. Attached to the

^{3.(...}continued)

for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

^{4.} The various forms used in the course of implementing the Settlement Agreement are commonly identified by their color.

Pink Form was a "Declaration of Prescribing Physician or Dispensing Pharmacy" that was completed by Ms. Swanigan's prescribing physician, Albert Brown, M.D., on August 24, 2000, hereinafter "Brown Declaration." Dr. Brown attested that he prescribed Pondimin and Redux to Ms. Swanigan, each in 250 mg dosages, to be taken one to two times daily. In the boxes requesting the approximate start dates for the prescriptions, Dr. Brown wrote "Jan. 5" but wrote "1998" and "1999" for the year. For the approximate end dates, Dr. Brown wrote "same" under the month heading and dashes under the day and year headings.

Ms. Swanigan submitted a Green Form dated January 10, 2003 to the Trust in which she stated that her medical condition entitled her to Matrix A-1, Level I Benefits. The Green Form was based upon a November 9, 2001 echocardiogram. The attesting physician indicated on Ms. Swanigan's Green Form that the echocardiogram showed that she had moderate mitral valve regurgitation⁵ and an ejection fraction of 50%-60%.

The Trust issued a deficiency notice to Ms. Swanigan dated September 11, 2003, which stated: "The Settlement Agreement requires proof of Diet Drug ingestion in order to process your GREEN Form. Although you included documents as proof of ingestion, they do not meet the requirements." R. at 235. Ms. Swanigan submitted several affidavits to the Trust in

^{5.} Moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement \S I.22.

response to the deficiency notice: (1) affidavit of Eleanor Taylor, Ms. Swanigan's mother; (2) affidavit of Lois Abdullah, Ms. Swanigan's co-worker; (3) affidavit of Robert Rosman, M.D., Ms. Swanigan's family doctor; and (4) affidavit of Ms. Swanigan.

Ms. Swanigan's affidavit stated that her physician dispensed Pondimin to her from November, 1999 until February, 2000. Both Eleanor Taylor and Lois Abdullah attested that they witnessed Ms. Swanigan taking a "pink tablet" between November, 1999 and February, 2000. Dr. Rosman stated that he knew Ms. Swanigan was being treated for weight loss by Dr. Brown but was not aware that she was being given Pondimin.

The Trust sent Ms. Swanigan a second deficiency notice on November 10, 2003. In response, she wrote to the Trust stating that "Dr. Albert Brown, no longer has a clinic. Through numerous attempts, I have not been successful in locating him." R. at 221. On May 17, 2006 the Trust called Ms. Swanigan to inquire about her diet drug prescription. She sent a letter to the Trust stating that she was dispensed Pondimin directly from Dr. Brown so that no prescription was ever written. R. at 219. On August 10, 2006, the Trust issued a tentative denial of Ms. Swanigan's claim. She contested that tentative determination, but on September 26, 2006 the Trust issued a Final Determination denying Ms. Swanigan's Matrix Level Benefits claim. She thereafter appealed the Trust's Final Determination and the matter was referred to arbitration. The arbitrator affirmed the

Trust's denial with a finding that Ms. Swanigan had failed to provide documentary proof of diet drug ingestion.

Ms. Swanigan raises two issues on appeal. She first argues the Trust should be estopped from rejecting the Brown Declaration. She maintains that the six years that elapsed from the time she submitted her Pink Form until the date the Trust issued its Final Determination prejudiced her because the delay prevented her from locating Dr. Brown and securing additional proof of ingestion. Second, Ms. Swanigan argues that the Pink Form constituted a written contract with Wyeth wherein it is agreed that she provided adequate proof of ingestion.

To prove estoppel Ms. Swanigan must show "a knowing misrepresentation by another party and reasonable reliance on that misrepresentation, causing a detriment to [her]." Peterson v. Nat'l Flood Ins. Program, 200 F. Supp. 2d 499, 505 (E.D. Pa. 2002). However, there is nothing in the record to establish that any misrepresentation was ever made. She was first notified on October 10, 2003 that her claim was deficient because the documents she included as proof of ingestion did not satisfy the Settlement Agreement. The Trust was consistent in its statements thereafter that Ms. Swanigan's proof of ingestion was deficient, and she has come forward with nothing to the contrary. Moreover, she had submitted her claim for Matrix Benefits on January 10, 2003, only nine months before she received the first deficiency notice. This is clearly not the six year delay Ms. Swanigan claims.

Her second argument that the submission of her Pink Form created a contract with Wyeth is also without merit. The Pink Form states: "The Settlement Agreement, including, without limitation its benefits and its release provisions, is incorporated by reference into this Individual Agreement as if fully set out at length." Pink Form 7. The Pink Form does not modify the Settlement Agreement in any way but is merely a means to implement it.

Under the Settlement Agreement the burden of proving ingestion remains at all times with the claimant. Proof of ingestion may be provided in three ways:

In order to complete the submission of a Claim and to qualify for any benefits under the Settlement Agreement, each Class Member must submit documentary proof to the Trustees and/or Claims Administrator(s) of the period of time for which the Diet Drugs Pondimin® and/or Redux™ were prescribed and dispensed to the Diet Drug Recipient who is the subject of the Claim. This proof must include one of the following:

- (1) If the diet drug was dispensed by a pharmacy, the identity of each pharmacy that dispensed Diet Drugs to the Diet Drug Recipient...and a copy of the prescription dispensing record(s) from each pharmacy...
- (2) If the diet drug was dispensed directly by a physician or weight loss clinic, or the pharmacy record(s) is unobtainable, the identity of each prescribing physician...and a copy of the medical record(s) prescribing or dispensing the diet drug(s)....;
- (3) If the pharmacy records and medical records are unobtainable, an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the Diet Drug Recipient, the drug(s) prescribed or

dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the Diet Drug(s).

Settlement Agreement § VI.C.2.d.

Ms. Swanigan claims that she was dispensed diet drugs directly from Dr. Brown. Since she has not provided medical records from him, she must rely on the affidavit from the prescribing physician allowed under § VI.C.2.d.(3) of the Settlement Agreement, that is, Dr. Brown's declaration, which she submitted with her Pink Form.

There are, however, numerous problems with the Brown Declaration that render it insufficient to prove ingestion. First, it is ambiguous regarding the time period during which Dr. Brown dispensed the diet drugs to Ms. Swanigan. Under the "approximate start date" Dr. Brown wrote "Jan. 5" and both the years 1998 and 1999. Under the approximate end date he wrote "same" under the month heading and dashes under the day and year headings. It is therefore impossible to tell when Dr. Brown started and stopped dispensing diet drugs to Ms. Swanigan.

Second, the Brown Declaration is inconsistent with Ms. Swanigan's affidavit regarding her dates of usage. According to Ms. Swanigan, Dr. Brown dispensed diet drugs to her from

^{6.} Although Ms. Swanigan has submitted other affidavits in support of her claim, they have no probative value here because the Settlement Agreement requires that only an affidavit from the "prescribing physician or dispensing pharmacy" can satisfy her burden of proof when the medical records are unavailable. See Settlement Agreement § VI.C.2.d.

November, 1999 through February, 2000. Even if we assume that Dr. Brown merely misread the headings on the declaration and meant that he prescribed diet drugs to Ms. Swanigan beginning on January 5, 1998 and ending sometime in 1999, this is contrary to Ms. Swanigan's own statements.

There are several other aspects of the Brown

Declaration that cast doubt on its veracity. By signing his declaration, Dr. Brown attested that he illegally dispensed

Pondimin and Redux to Ms. Swanigan. Under the most favorable reading of the Brown Declaration, Dr. Brown began dispensing the diet drugs to Ms. Swanigan in January 5, 1998, which is almost four months after the Government removed the drugs from the market. If we credit Ms. Swanigan's statements, he began dispensing the diet drugs to her more than two years after they were pulled from the market.

Moreover, the Brown Declaration states that the diet drugs were dispensed to Ms. Swanigan in 250 mg dosages to be taken one to two times per day. This cannot be correct. Pondimin was only issued in 30 mg pills and Redux in 25 mg pills.

In sum, the Brown Declaration is of no value to Ms. Swanigan's claim. Since she has not provided sufficient proof of ingestion, we will affirm the Report and Award of the Arbitrator.

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AND NOW, this 15th day of April, 2008, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the Report and Award of the Arbitrator Mark A. Sargent, Esq., is AFFIRMED and appellant, Denise Swanigan, is not entitled to Matrix Level Benefits under the Diet Drug Nationwide Class Action Settlement Agreement.

BY THE COURT:

/s/ Harvey Bartle III